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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/800.364 11/26/91 HEWICK

R 5182A

EXAMINER

FURMAN, K

ART UNIT

PAPER NUMBER

18

18M2/0407

LEGAL AFFAIRS DEPT.
GENETICS INSTITUTE, INC.
87 CAMBRIDGE PARK DR.
CAMBRIDGE, MA 02140

1814

DATE MAILED:

04/07/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 1/13/94 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), - days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1-35 are pending in the application.

Of the above, claims 1-5, 10-12 and 20-25 and 34 are withdrawn from consideration.

2. ☐ Claims have been cancelled.

3. ☒ Claims 7, 8, 14 and 15 are allowed.

4. ☒ Claims 6, 9, 13, 16-19 and 26-33 and 35 are rejected.

5. ☐ Claims are objected to.

6. ☒ Claims 34 ¹⁵ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on , has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed , has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on .

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

07/800.364

Part III DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §1.821(a) and (a)(2). However, this application fails to comply with one or more of the requirements of 37 CFR §§ 1.821 through 1.825 as follows: This application does not conform exclusively to the requirements of §§ 1.821 through 1.825. The non-conforming material should be deleted (§1.821(b)). The bovine sequence of native BMP-8 set forth on p. 33 in Table 4, while identified with regard to the sequence differences from the human homolog with respect to SEQ ID NO: 14 on p. 32 and not required for examination, must either be deleted or, preferably, a new Sequence Listing and CRF must be provided including this sequence since the sequence is actually shown on p. 33 of the specification. All sequences actually shown should be in the Sequence Listing.

RESPONSE TO AFFIRMATION OF RESTRICTION REQUIREMENT

2. Applicant's election without traverse of Group II in Paper No. 15 is acknowledged.

Claims 1-5, 10-12 and 20-25 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Election was made without traverse in Paper No. 15.

While applicants state at the bottom of p. 10 of the instant amendment that claims 1-5, 10-12 and 20-25 have been deleted, there is no specific amendment directing the cancellation of these claims and it is stated at the bottom of p. 11 that the claims are merely "withdrawn". Clarification is requested.

Newly submitted claim 34^{is} directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The Invention of the instant DNAs, host cells and methods of producing BMP-8 proteins and the invention of

Art Unit: 1814

new claim 34 directed to a method for isolating a DNA sequence (separately classified in Class 435, subclass 6) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products can be used to produce the BMP-8 protein for use as a drug.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 34 is also withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

OBJECTIONS/REJECTIONS WITHDRAWN

3. The specification is objected to under 35 U.S.C. § 112, first paragraph, as set forth in paragraph 24 of the last Office Action, is withdrawn in view of the instant amendments and applicants' arguments.

The rejection of Claims 17 and 18 under 35 U.S.C. § 112, first paragraph, as set forth in paragraph 26 of the last Office Action, is withdrawn in view of the instant amendments.

The objection to the specification and rejection of claims 9 and 18 under 35 U.S.C. § 112, first paragraph, as set forth in paragraph 27 and 28 of the last Office Action, is withdrawn in view of the instant Declaration of Deposit Requirement including the required statements by the attorney of record.

Art Unit: 1814

The rejection of Claims 6-8, 13-15 and 19 under 35 U.S.C. § 112, second paragraph, as set forth in paragraph 29 of the last Office Action, is withdrawn in view of the instant amendments.

The rejection of Claims 6, 9, 13 and 16 under 35 U.S.C. § 101, as set forth in paragraph 32 of the last Office Action, is withdrawn in view of the instant amendments and applicants' arguments.

NEW OBJECTIONS/REJECTIONS

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9, 16, 18 and 35 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 and those dependent thereon are indefinite and/or not enabled because that deposited as ATCC #75010 and #75011 are microorganisms having numerous DNAs and it is unclear which DNA applicants are referring to. The specification does not enable how to make and use the broad scope of all isolated DNAs of the deposited microorganism because the function of such DNAs and the proteins encoded is not disclosed or supported with respect to how to make and use them without undue experimentation. Additionally, claim 18 now expectedly reads upon a significant number of inoperative species because those skilled in the art would question whether the proteins encompassed in general would have the useful activity of the native BMP-8 protein having the native sequence for the reasons

Art Unit: 1814

previously discussed. Broad claim may be rejected merely because it reads on a significant number of inoperative species when examiner sets forth reasonable grounds in support of his or her conclusions that the claims may read upon inoperative subject matter and it becomes incumbent upon applicant either to reasonably limit claims to approximate area where operativeness has not been challenged or to rebut examiner's challenge by submission of representative evidence or by persuasive arguments based on known laws of physics and chemistry (see In re Cook and Merigold, 169 USPQ 298 (CCPA 1971)).

6. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 17-19, 26, 27 and 33 rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent 4,886,747 of Derynck et al. (AS). Derynck (cited by applicants after the first action) discloses the recombinant expression of TGF- β comprising culturing a cell transformed with a vector comprising a DNA encoding TGF- β in operative association with expression control sequences and the recovery, isolation and purification of the protein encoded by the DNA from the culture media (see Example 5). While Derynck et al. did not disclose the DNAs or proteins of the claims, claims 17-19, 26, 27 and 33 are drawn to the use of a new but similar product in an old process

Art Unit: 1814

of making which is not a patentably different process because the only difference between the process known in the art and the claimed process is the new product of applicants' claimed invention which would have been expected to work in the known process. See In re Durden 226 U.S.P.Q. 359 (Fed. Cir. 1985) and Ex parte Ochiai, 24 USPQ2d 1265 (BPAI, 1992). See also columns 19-21 of Kuberasampath et al. (AT) and col. 33 of Parsons et al. (which references are not required and not relied upon in the rejection but cited as further evidence) which further show that sequences of the family of proteins to which the instant sequence(s) belongs would have been expected to work in the known process, especially in view of the known homology between the members of this family and TGF- β .

OBJECTIONS/REJECTIONS MAINTAINED

7. Applicant's arguments filed 1-13-93 have been fully considered but they are not deemed to be persuasive.

8. The rejection of Claims 6, 13 and 17 (now Claims 6, 13, 17, 29-33 and 35) under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to where the DNA of the claims encodes a protein having at least the sequence of amino acids that is encoded by nucleotide #430 through #843 of Figure 2, as set forth in paragraph 25 of the last Office Action is again made and maintained.

Applicants' arguments are on the grounds that the limitation to include all of a), b) and c) which form part of the nucleotide sequence of BMP-8 should be enabled and obviate the rejection. However, these arguments are not persuasive because this is not what the Examiner had set forth as being enabled and applicants have not addressed the Examiner's arguments with regard to why that which is now claimed should be enabled in spite of those arguments. Further, the sequences of the claim are not known to be particularly correlated with the activity of the intact protein and it has not been shown that a protein merely containing these portions would have the requisite activity.

Art Unit: 1814

Additionally, even if such correlation and activity were shown, those skilled in the art would question whether these sequences in any order would produce an active protein due to possible steric hindrances, improper folding and/or incorrect juxtapositioning of critical regions. The limitations to include molecular weight limits does not narrow the scope so as not to require undue experimentation since the intervening portions which are not in the required portions (which can be any sequence) still encompasses an extremely large or essentially infinite number of species combinations and includes regions which may be required for useful activity. Additionally, claim 17 now expectedly reads upon a significant number of inoperative species because those skilled in the art would question whether the proteins encompassed in general would have the useful activity of the native BMP-8 protein having the native sequence for the reasons previously discussed.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Claims 7, 8, 14 and 15 are allowed.

11. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE

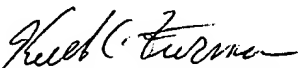
Art Unit: 1814

EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Papers relating to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center number is (703) 308-4227. Papers may be submitted Monday-Friday between 8:00 am and 4:45 pm (EST). Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Furman whose telephone number is (703) 308-3453. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 6, 1994


KEITH C. FURMAN, Ph.D.
PRIMARY EXAMINER
GROUP 1800